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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,453	10/07/2003	Randal A. Stevens	136.0110001	4505
<div>38356 7590 01/09/2008 BROOKS, CAMERON & HUEBSCH, PLLC 1221 NICOLLET AVENUE, SUITE 500 MINNEAPOLIS, MN 55403</div>				
			<div>EXAMINER PADGETT, MARIANNE L</div>	
			<div>ART UNIT 1792</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE 01/09/2008</div>	<div>DELIVERY MODE PAPER</div>

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/680,453

Applicant(s)

STEVENS ET AL.

Examiner

Marianne L. Padgett

Art Unit

1792

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

1. Applicants' amendment has corrected the 112 first & second problems as set forth in sections 2-4 of the action mailed 12/29/2006, however has created some new problems as set forth below.
2. Claims 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear how a thickness whose dimension has already been required to be set to approximately 0.10 mm, can be said to depend on any property, i.e. viscosity or "build temperature" (meaning undefined). The examiner notes that new claims 15-18 derive their support on page 4, lines 17-19 in the specification, from the phrasing/meaning therein, it appears that it would have been more accurate & meaningful to have the limitation of claim 15 (i.e. the specific thickness) dependent from the limitation of the thickness depending on the properties of the UV curable substance (i.e. claims 16).

Also, while the examiner can guess at the intent of "build temperature", it has no clear or necessary meaning, with "build" used as an adjective implying that it is somehow related to the deposition or construction of the object, but its scope, metes and bounds, or actual relationship is unclear.

Furthermore, the "gloss exterior finish" is describing the surface texture of the object, specifically the surface texture of the layer deposited on the object, but the finish is NOT the layer itself, and page 4 of applicants' specification clearly indicates that the taught thickness (which is the value claimed) is up the layer, NOT the finish, although the examiner is uncertain if the taught typical 0.10 mm thickness is supposed to be the resin layer thickness as deposited, or after completion of the process, where the examiner notes the layer thicknesses for both states would have been important to one ordinary skill in the art in considering the final product, dependent on the particular material & how curing affects that materials volume or shrinkage.

3. Claims 14-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the

specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 14 requires "... finish on the... shell **prevents** buildup of cerumen (ear wax), dirt, and perspiration all on... shell" (emphasis added), however page 3, lines 14-16 of the original specification teaches that it is "less susceptible", which is a different scope & effect, since preventing includes active participation, such as causing cleaning actions, thus the scope of this claim is broader than taught by the original specification, hence encompasses **New Matter**. Also note that the specification teaching of "less susceptible" does not say what alternative is being compared to, although page 2, lines 14-19 discuss buildup problems with respect to matte finishes, providing a taught comparison.

As discussed above in section 2, the claimed thickness for the "finish", rather than for the deposited or totally cured layer, would appear to be **New Matter**, as it is not supported by the original specification, since the "finish" is only the top surface of the external layer, and the claimed thickness was only disclosed for that layer, not its surface.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner

to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-2 & 4-20 are rejected (claims 4-5 & 8-9 tentatively) under 35 U.S.C. 103(a) as being unpatentable over Hanna (6,660,208 B2 = 2004/0028253 A1 = EP 124536982), in view of Farnworth et al (6,482,576 B1) as set forth in sections 4 of the actions mailed 12/8/2005 & 6/30/2006.

The claims to require the initial step of the shell being created by stereolithographically processes, then coating the ear shell to create a surface layer, however all the applied references create the body of their product via stereolithographically techniques as previously discussed, and it was further noted that Farnworth et al., who teach a specific process for improving the overall surfaces of a body made by stereolithographic techniques, does so by lifting the multilayered structure out of the photopolymer bath, which process is equivalent of applicant's claim of creating a layer on a stereolithographically made structure. Farnworth et al. as previously noted then proceeds to drain excess liquid therefrom, which is the equivalent of applicants' step "to drain off... leaving an uncured layer", hence these steps are not considered to provide any unobvious step that may produce any unexpected results to the process, especially as Farnworth et al.'s technique is taught to be generally applicable to the fabrication of stand-alone structures (col. 4, lines 19-23 & col. 14, lines 39-49) and Hanna particulate notes the conventionality of coating hearing aid shell bodies, such that Farnworth et al. provides an efficient means of effecting this conventional known procedure, while providing advantages as taught therein. As previously discussed, as this surface overcoating suggested by this combination of references is also UV cured & of the same UV curable material as employed in constructing the body, thus it would have been expected to require the alcohol extraction technique of Hanna et al., where it would have been obvious to one of ordinary skill in the art that by employing Farnworth et al. smoothing technique to coat the stereolithographically object, that one would employ the extraction/detoxification technique with alcohol, etc., after this overall surface coating technique, as that would be the most logical and effective

way to proceed given the teachings, and would be in keeping with Farnworth et al.'s teachings concerning reducing quantity of polymers consumed in combination with production of smooth walls (col. 14, lines 50-57).

To reiterate, Hanna teaches making hearing aid shells via stereolithographic techniques, where in order to produce biocompatible products, it is necessary to detoxify by extracting cytotoxins remaining from the stereolithographic polymerization procedures, which may involve UV curing. Several different means of doing so are taught, which are inclusive of extracting with alcohols, such as isopropyl alcohol alone, or with use of such alcohols in ultrasonic bath, with teachings on sufficient times for these procedures to extract unpolymerized residues from the stereolithographically constructed hearing aid shells, which affects required detoxification. Thereafter, post UV curing finishes the cure of the produced shell, and it is further taught that it is common practice to further coat hearing aid shells, such as with UV curable lacquer. In Hanna (EP), see the abstract; figures 2-3 & 7; [0001]; [0005]; [0009-10]; [0012]; [0014-15]; [0022-23]; [0030-33]; especially [0039]; and [0042-49]. It is further noted that [0042] discusses considerations of build layer thickness for these stereolithographic techniques, where 0.075 mm were used for high resolution, but that the techniques (& resins used therefore) were considered generally capable at 0.25 mm thicknesses.

While Hanna uses an analogous series of steps to applicants' procedure of UV polymerization and extraction/removing for constructing the hearing aid shell, they differ by not giving any similar details for their generically disclosed UV curable coating of that shell. However, Farnworth et al. teach a procedure for coating stereolithographic structures, where they teach their process is applicable to any structure made by stereolithography, which is advantageous for smoothing the surface to get rid of crevices at the layer interfaces on the surface, which are undesirable as they may be unsightly and they may collect dust, dirt and moisture, which is considered to be overlapping with the claim of preventing dirt & perspiration built up. When Farnworth et al. lift the structure in its final form from the stereolithographic polymer

bath, instead of washing any unpolymerized resin from the crevices, they merely drain the excess polymer from the structure so as to leave a coating that fills the crevices, reading on applicants' "uncured layer", then they cure by either UV laser or broad beam or flood type UV radiation, after which typical final curing procedures, including washing with alcohol and UV post curing may be performed. In Farnworth et al., see the abstract; figures 1 & 6-10; col. 1, line 7-18; col. 2, lines 13-25 & 61-67; col. 3, line 41-col. 4, line 23; col. 5, line 52-col. 6, line 17; col. 8, line 49-col. 9, line 5+; col. 11, line 35-col. 14, line 68, especially col. 12, lines 1-40 & 58-67, col. 13, lines 5-35 & 48-col. 14, lines 13 & 39-57.

It would have been obvious to one of ordinary skill in the art to use the surface smoothing coating procedure of Farnworth et al. to produce the stereolithographic hearing aid shells of Hanna, in order to achieve the advantageously smooth surface as taught in Farnworth et al., as it provides a specific procedure for creating the suggested UV cured coating, and further provides the advantageous elimination of crevices that can collect dirt, as well as being economical in its use of photo polymeric resin, which is not wasted by washing away, and in consideration of how this coating procedure enhances wall uniformity, affecting the size of final object. It would have been further clear to one of ordinary skill in the art, that one would use the detoxification procedures (i.e. use of alcohol in ultrasonic bath or to chemically extract undesirable unpolymerized residues after the initial UV cure) of Hanna on the so produced coating of the stereolithographically produced hearing aid shell, in order to have a biocompatible product after final cure, as the reasons for performing the extraction (\equiv removing excess) would have been equally applicable to the UV cured overcoating, as to the UV cured body of the shell.

With respect pre-sizing, as previously discussed and paraphrased, in any process that requires the article being made to have a precise size in the end product, i.e. with the tolerances for the size produced are extremely small, any competent technician, let alone designer, would have been expected to figure in the thickness of a coating being applied over the exterior of the item, when calculating the size of the substrate to be coated. It would have been a matter of basic complements to do so with the claimed

"ear shell", as it is conventional in the art to make this individualized to the person, i.e. the tolerances for what will fit in not fit our small. Claiming a limitation that would be done as a matter of course by any competent practitioner, cannot be considered to provide a patentable limitation to a process.

The examiner additionally notes that as both Farnworth et al. & Hanna are directed to stereolithographically processing of custom designed objects (Farnworth et al.-col. 2, lines 12-26 & 60-67+, especially 18-20 & 61-63; Hanna-(EP)-abstract, [0004], specifically directed to hearing aid shells), that there are essentially two ways to get that custom-designed shape/size correct, either make it to the correct dimensions the first time, or to machine it down to size afterwards. There would be no point in using the stereolithographic techniques of these references to build up a shape to a size that was not the desired size, inclusive of the coating applied to the layered object, as it is part of the layered object, i.e. just another layer, and any competent practitioner would readily realize that it had to be included in the design calculations for the overall shape & size, if one was not going to have to machine the shape down to the appropriate size after final layer deposition (& cure). As the primary reference to Hanna specifically teaches that one of the advantages of the stereolithographic process is to eliminate the need for machining ((EP)-end of [0004]; or in (208) col. 2, lines 1-26, especially 19-22) with specific teaching of the shell itself being coated with UV curable lacquer ((EP)-[0039]; or in (208)-col. 8, lines 55-60), any overcoating layer(s) would have been expected to be considered included when this customized object's required size was determined, including all layers deposited, both body and overcoating, otherwise one would be required to either machine the end product (which Hanna teaches against) or have a fatally defective product, i.e. one that does not can fit one's customer's ear or the like.

Applicant has previously appeared to object to the examiner's characterization of a competent technician, let alone the designer, having been expected to figure in the surface coating thickness in calculating the size of the substrate which will be coated to form the final object, saying that the examiner failed to identify what would be the ordinary skill of someone in the art. An ordinary technician (or

engineer) who is making/designing a customized object as required by either of these references, who failed to "pre-sized" or measure their customers required dimensions & to use those previously obtained/calculated final dimensions (inclusive of all layers, stacked or overcoated, that form the final object) in performing an additive process (i.e. stereolithographic process), would likely be fired for incompetence, since as pointed out by the primary reference to Hanna, one of the points of using stereolithographic processing is to avoid or to eliminate the need for machining, which would necessitate taking into account ALL layers.

Applicants have added new claims to processing limitations of the Finnish thickness, by which in light of the specification, they presumably meaning the exterior layer thickness, and curing times for initial & post (after alcohol bath or like) curing steps.

With respect to layer thickness, Farnworth et al., like Hanna, teach for the initial stereo graphic construction that thinner built-up layers provide high-resolution, noting useful thicknesses are 0.001-0.0300 inches, or preferably 0.002-0.020 inches, where like dimensions are also taught for the smoothing layer (ref.#16) for the vertical sides (ref.#54) of stereo optically constructed articles (column 6, lines 50-62; column 8, lines 33-36 & 62-68; figure 4). Note as illustrated, the needed layer thickness for the smoothing effect will clearly depend on the resolution of the stereolithographic structure, thus the layer thickness used therefore would have been expected to be determined considering such structural characteristics, in combination with properties of the resin or photopolymer been deposited. That properties such as viscosity or deposition temperature (which will generally affect the viscosity), will affect the ability to deposit various thicknesses from a solution is an old and well-known principle, that would have been expected to be taken into account by one of ordinary skill in our art, especially as stated by Farnworth et al. "methods... four... layer thickness control or known in the art" (column 8, lines 33-36).

With respect to the specific cure times of 3 minutes for the initial cure & 30 minutes for the final cure, the examiner notes that cure times are dependent on specific polymers employed (unspecified),

various UV parameters, such as intensity &/or source characteristics (unspecified), etc., hence one of ordinary skill in the art would have been expected to consider such known effects & apply routine experimentation to determine times for specific polymers, thicknesses, curing sources employed, etc., taking into consideration the need to totally cure, so that no residual unpolymerized material remains, as is consistent with discussions of problems from remaining uncured materials as present in the combined references. While Farnworth et al. does not specify particular times for the final surface cure, they clearly specify full cure is required & when discussing use of laser to achieve cure, note that the angle of incidence in accordance with the angles formed by the layer structure crevices are considered in order to insure the full cure, hence given such teachings, it would've been abundantly clear to one of ordinary skill in the art to optimize curing times dependent on material & UV source employed in order to insure full cure. With respect to specifically claim times, giving complete lack of any context to provide significance to the times (material, UV source, UV parameters, etc.) or any criticality attributed to the specific times that may be generalized to all polymers & all curing sources at all parameters, these times would appear to have little significance in and of themselves.

6. Other previously cited art that interest included: Widmer (7,014,010 B2; column 3-6, especially column 6, lines 19-40), Mullenborn et al. (7,142,682 B2; stereolithography -customization & avoids use of multiple techniques to form housing), & Feeley et al. (7,016,512 B2; column 20), who provide additional teachings on customizing hearing aid components via use of stereolithography. The publications to Haussmann (2006/0140430 A1) & Bachler et al. (2006/0233384 A1) are also of interest to the state of the art for stereolithographic formation of hearing aid components, but are not prior art.

Sauerhoefer (5482659) was cited, who teach a stereolithographic process including post-processing steps of submerging in alcohol with ultrasonic agitation, drying & UV post-treatment curing. Johnson et al. (2005/0175925 A1) teach a specific composition and structure of photocurable material for

making three the objects with generally smooth surfaces when cured, which may be used for making housings for hearing aids (abstract & [0011], etc.).

7. Applicant's arguments filed 10/12/2007 & discussed above have been fully considered but they are not persuasive.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne L. Padgett whose telephone number is (571) 272-1425. The examiner can normally be reached on M-F from about 8:30 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks, can be reached at (571) 272-1423. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair->

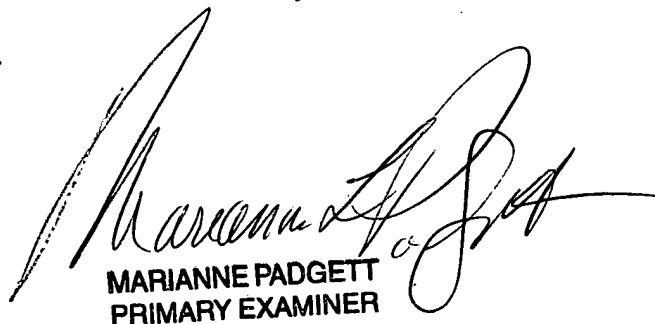
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1/6-7/2008



MARIANNE PADGETT
PRIMARY EXAMINER